DEC 2 4 2013

510(k) Summary
for the VELOX Anterior Cervical Plate

In accordance with 21 CFR 807.92 of the Federal Code of Regulations
the following 510(k) summary is submitted for the VELOX Anterior Cervical Plate

Date Prepared: 5/17/2013

Submitter:
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Contact Person:
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Director of Regulatory Affairs.
SpineCraft, LLC
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Establishment Registration No:	3004717358
Trade name:	VELOX Anterior Cervical Plate System
Common Name:	Anterior Cervical Plate
Classification Name:	Spinal intervertebral body fixation orthosis Per 21 CFR 888.3060
Product Code:	KWQ Class II
Classification Panel:	87

Predicate or legally marketed devices which are substantially equivalent:
Envision Anterior Cervical Plate System (K020649) / Ortho Development
ALTUM Anterior Cervical Plate (K103505) / SpineCraft
C-Tek MaxAn Anterior Cervical Plate System (K080646) / Biomet Spine
UNIPLATE Anterior Cervical Plate (K042544 / K082273 / K100070) / DePuy
CLSP Cervical Plate (K000536) / Synthes

Description of the device:
The VELOX Anterior Cervical Plate System is intended for anterior screw fixation of the plate to the cervical spine. The fixation construct consists of a cervical plate that is attached to the vertebral body of the cervical spine with self-tapping bone screws using an anterior approach. The VELOX anterior cervical plate, screws and instruments were designed taking into consideration the whole procedure. Plates are available in a variety of lengths, addressing multiple levels of fixation. The VELOX plate incorporates vision ports that allow visualization of post-operative endplate/graft incorporation. Alignment notches on the cephalad and caudal ends of the plate facilitate precise midline placement and allow for Temporary Pin fixation of the plate. To accommodate normal cervical spine lordosis and, at the same time, minimize the need for additional plate contouring, the VELOX Anterior Cervical Plate comes with a pre-machined lordotic curve. Bone screws are available for fixed angle or variable angle implantation in a variety of lengths.

Materials:
Ti-6Al-4V per ASTM F136
CoCr28Mo6 per ASTM F1537

Function:
The VELOX Anterior Cervical Plate system is indicated for use in the temporary stabilization of the anterior spine during the development of cervical spinal fusion.

Substantial equivalence claimed to predicate devices
VELOX Anterior Cervical Plate system is substantially equivalent to the Envision Anterior Cervical Plate System (K020649), ALTUM Anterior Cervical Plate (K103505) and MaxAn Anterior Cervical Plate System (K080646) in terms of intended use, design, materials used, mechanical safety and performances. The table below compares the features and characteristics of the VELOX Anterior Cervical Plate system to these predicate devices.

Intended Use:
The VELOX Anterior Cervical Plate System is intended for anterior screw fixation to the cervical spine. It is to be used in skeletally mature patients as an adjunct to fusion of the cervical spine (C2 to C7). The system is indicated for use in the temporary stabilization of the anterior spine during the development of cervical spinal fusion in patients with:

- degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies),
- spondylolisthesis,
- trauma (i.e. fractures or dislocations),
- tumors,
- deformity,
- pseudarthrosis,
- failed previous fusion,
- spinal stenosis.

Non-clinical Test Summary:
The following tests were conducted:

ASTM F1717-12, "Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model." Testing included Static Compression Bending Tests, Static Torsion Tests and Dynamic Compression Bending Tests. The results of this testing were compared to predicate systems, with the results being equal or higher than the predicate systems.

Clinical Test Summary
No clinical studies were performed

Conclusions Nonclinical and Clinical
The VELOX Anterior Cervical Plate System is substantially equivalent to the predicate devices in terms of indications for use, design, material, and function.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 24, 2013

SPINECRAFT, LLC
Ms. Ami Akallal-Asaad
Director of Regulatory Affairs
777 Oakmont Lane
Westmont, Illinois 60559

Re: K131521
Trade/Device Name: VELOX Anterior Cervical Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: November 21, 2013
Received: November 26, 2013

Dear Ms. Akallal-Asaad:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K131521

Device Name
VELOX Anterior Cervical Plate System

Indications for Use *(Describe)*

The VELOX Anterior Cervical Plate System is intended for anterior screw fixation to the cervical spine. It is to be used in skeletally mature patients as an adjunct to fusion of the cervical spine (C2 to C7). The system is indicated for use in the temporary stabilization of the anterior spine during the development of cervical spinal fusion in patients with:

- degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies),
- spondylolisthesis,
- trauma (i.e. fractures or dislocations),
- tumors,
- deformity,
- pseudarthrosis,
- failed previous fusion,
- spinal stenosis.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Anton E. Dmitriev, PhD

Division of Orthopedic Devices

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